(iii) *Limitations*—(*a*) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(*b*) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(*c*) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(*d*) Flumethasone may be administered to animals with bacterial diseases provided appropriate antibacterial therapy is administered simultaneously.

(*e*) The drug is not to be used in horses intended for slaughter for food purposes.

(*f*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intralesionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflamation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shocklike states by intravenous administration.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

(3) *Cats*—(i) *Amount.* 0.03125 to 0.125 milligram daily intravenously, intramuscularly, or subcutaneously.

(ii) *Indications for use.* It is used for the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

[44 FR 16011, Mar. 16, 1978, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See No. 000061 for use as in paragraph (e) of this section.

(2) See Nos. 055529, 057561, and 059130 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

(3) See No. 000856 for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.5 mg per pound (/lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle*—(i) *Amount.* (A) 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into two doses administered at 12-hour intervals, intravenously, for up to 3 days.

(B) 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.

(ii) *Indications for use.* (A) For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For No. 000061: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529, 057561, and 059130: Not for use in lactating or dry dairy cows.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003; 69 FR 53618, Sept. 2, 2004; 69 FR 60308, Oct. 8, 2004]

§ 522.995 Fluprostenol sodium injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 0.55 microgram fluprostenol per kilogram of body weight.

(2) *Indications for use.* The drug is used in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(3) *Limitations.* Administer by intramuscular injection only. *Warning:* Not for use in horses intended for food. For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Fluprostenol is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

[44 FR 52191, Sept. 7, 1979, as amended at 47 FR 22092, May 21, 1982]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications.* Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor.* See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use.* For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations.* For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor.* See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use.* The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations.* Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997]